

REMARKS

The Office Action

Claims 1-3 and 5-9 are pending in this application. Claims 3 and 5-9 are withdrawn from consideration. Claims 1 and 2 are rejected under 35 U.S.C. § 112, first paragraph, for new matter. Claims 1 and 2 are also rejected under 35 U.S.C. § 102(e) for lack novelty over Sanberg et al. (U.S. Patent Application Publication No. 2004/0197310; hereinafter "Sanberg") as evidenced by Ha et al. (U.S. Patent Application Publication No. 2005/0118714; hereinafter "Ha"), and under 35 U.S.C. § 103 for obviousness over Pittenger et al. (WO 99/03973; hereinafter "Pittenger") as evidenced by Erices et al. (British Journal of Haematology 109:235-242, 2000; hereinafter "Erices"). By this reply, Applicant cancels claims 3 and 5-9, and addresses each of the rejections.

Interview with Examiner Nguyen and Examiner Woitach

Applicant's representatives wish to thank Examiners Nguyen and Woitach for their participation in an in-person interview dated October 16, 2007. As acknowledged by Examiners Nguyen and Woitach, present claims 1 and 2 are in condition for allowance, and Applicant respectfully requests the mailing of a notice to that effect. If the Office does not agree, Applicant respectfully requests that the Office contact the undersigned by telephone in order to resolve any remaining issues in this case.

Rejection under 35 U.S.C. § 112, first paragraph

The Office rejects claims 1 and 2 for lack of written description in view of Applicant's

amendment to claim 1 to include the phrase “USSCs regenerate cardiac muscle in said patient and treat said disease.” Applicants respectfully traverse this rejection.

As was discussed during the in-person interview, and acknowledged by Examiners Nguyen and Voitach, support for the amendment to claim 1 is found in original claims 1 and 4, which describe a method for treating a disease of the cardiac muscle by administering USSCs to a patient, and in the specification at, e.g., page 7, lines 22-24, which teaches that the invention provides a medicament that is a “regenerative therapeutic.” In addition, Applicant provided evidence demonstrating that USSCs, when administered to a mammal, regenerates cardiac tissue by engrafting in the heart, differentiating into cardiac tissue, and restoring cardiac function (see Declaration of Morey Kraus filed with the Reply to Office Action on April 27, 2007). For all these reasons, Applicant submits that the specification, as filed, provides written description support for each limitation recited in present claim 1. Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 U.S.C. § 102(e)

The Office also rejects claims 1 and 2 under 35 U.S.C. § 102(e) for anticipation by Sanberg. As was explained during the in-person interview, the present application is entitled to claim benefit to the filing date of U.S. Serial No. 09/985,335 (hereinafter the “‘335 application”), which is November 2, 2001. Moreover, the ‘335 application provides full written description support for present claims 1 and 2. Accordingly, Sanberg, which has a priority date of February 12, 2003, is not prior art to the present application; this fact was acknowledged by Examiners Nguyen and Voitach during the in-person interview. This rejection can be withdrawn.

Rejection under 35 U.S.C. § 103

The Office rejects claims 1 and 2 for obviousness over Pittenger in view of Erices. As was discussed with, and acknowledged by, Examiners Nguyen and Woitach during the in-person interview, neither Pittenger nor Erices teaches or suggests the administration of USSCs from cord blood to a patient to treat cardiac muscle disease. Pittenger only describes the use of MSCs from bone marrow for cardiac muscle regeneration and Erices does not teach or suggest the use of USSCs for treating cardiac muscle. Examiners Nguyen and Woitach further acknowledged that USSCs are distinct from MSCs. This determination was made, in part, based on evidence supplied by Applicant in connection with the '335 application showing that MSCs express hyaluronan synthase but USSCs do not (see Declaration of Morey Kraus filed on April 27, 2006; a copy of which is provided); this distinguishing feature is recited in present claims 1 and 2.

Applicant also explained that Erices was removed as prior art against composition of matter claims 1 and 9 of the '335 application, based on evidence presented in the Declaration of Peter Wernet under 37 C.F.R. § 1.131 filed on March 11, 2004, which shows Applicant's conception and reduced to practice of USSCs prior to the publication of Erices. As requested by Examiners Nguyen and Woitach, Applicant provides a copy of this Declaration.

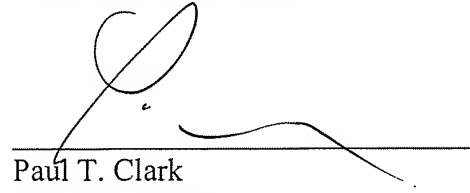
This rejection can be withdrawn.

CONCLUSION

Applicant submits that claims 1 and 2 are in condition for allowance, and such action is requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,



Paul T. Clark
Reg. No. 30,162

Date: October 24, 2007

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045